Egypt: New Registration Requirements for Imported Pharmaceutical Products

Jihan Labib
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Effective January 15, 2009, the Egyptian Ministry of Health has started to implemented new registration requirements for imported pharmaceutical products. Following are the new requirements:

Registration Requirements for Imported Pharmaceutical Products (New Products):

- Company profile; contain comprehensive information about the manufacturing company that should be updated regularly after any change.
- Registration application.
- A certificate indicating that the product is already registered and freely sold from the American FDA or the European EMEA or the Japanese JPMA. In addition, the company should be a member in the ICH. The certificate should be original, authenticated and legalized from the Egyptian Embassy.
- The cost list and the importation price (CIF or FOB) and the product price in the country of origin (original, authenticated and legalized from the Egyptian Embassy).
- Product price in other countries.
- The original product pack (outer and inner pack) with insert.
- List of countries the product registered in.
- The FSC (Free Sale Certificate) in the country of origin (original, authenticated and legalized from the Egyptian Embassy).
- The source of the API and in case the source is changed a relative invitro equivalence study should be submitted.
- Certificate of analysis for all API.
- Certificate of analysis for the finished product.
- Stability study for the product.
- The agency agreement (original, authenticated and legalized from the Egyptian Embassy).
- Bioequivalence study for generic products.
- Technical file for the product.
- Soft copy (CD) of all the previously mentioned documents.

In case of Re-Registration:

- Re-registration form.
- The updated original pack + insert.
- The registration certificate of the product.
- The pricing certificate of the product.
- Product composition (active and inactive materials) with concentrations on company paper and authorized.
- Real time stability study.
- Recent certificate of analysis of the product.
- Copy of certificate of conformance for the product from the national control lab.
- Recent FSC from the country of origin (original, authenticated and legalized from the Egyptian Embassy).
- Soft copy (CD) of all the previously mentioned documents.

For Biological Products:

- The CPP certificate on the WHO format (original, authenticated and legalized from the Egyptian Embassy and the Chamber of Commerce in the country of origin).
- FDA certificate – if available - on the WHO format (original, authenticated and legalized from the Egyptian Embassy and the Chamber of Commerce in the country of origin).
- EMEA certificate – if available - on the WHO format (original, authenticated and legalized from the Egyptian Embassy and the Chamber of Commerce in the country of origin).
- Plasma master file.
- Flow chart for the manufacturing process indicating the manufacturing sites.
- Flow chart indicating the plasma source – from plasma collection till the finished product.
- The Egyptian MOH inspection report.
- The agency agreement (original, authenticated and legalized from the Egyptian Embassy and the Chamber of Commerce in the country of origin).
- Material composition of the finished product.
- Certificate of analysis of the finished product.
- Method of analysis of the finished product.
- Stability study for the finished product and API in the recommended storage conditions.
- Preclinical studies.
- Clinical studies.
- Post marketing studies.
- Certificate of the plasma source.
- The outer and inner pack with insert.
- The container closure system type and specification.
- The manufacturing method including the in-process controls and validation studies performed.
- Material specification for all active and inactive materials and related test methods with test method validation.
- Finished product specification and test methods validation.
- International Reference for the finished product.
- Declaration from the company that the raw materials are free from the BSE and TSE.
- Viral safety validation studies.
- List of countries that the product is freely sold in.
- Product price file.

In addition the company documents:

- Company profile.
- Site master file for the manufacturing facility.
- The site license original, authenticated and legalized from the Egyptian Embassy and the Chamber of Commerce in the country of origin).
- GMP certificate (original, authenticated and legalized from the Egyptian Embassy and the Chamber of Commerce in the country of origin).
- GMP certificate from any other country or organization.
- Product portfolio for the manufacturing company.
- Summary of the research activities in the company.
- List of other registered products for the registration party.

Resources & Key Contacts

U.S. Commercial Service in Egypt: http://www.buyusa.gov/egypt/en/
U.S. Embassy: http://cairo.usembassy.gov/

USAID: http://www.usaid-eg.org/
World Bank: http://www.worldbank.org/
American Chamber of Commerce in Egypt: http://www.amcham.org.eg
Egyptian Government Web Portal: http://www.egypt.gov.eg/english/
Ministry of Health & Population: http://www.mohp.gov.eg/
Medical and healthcare market reports on Egypt: http://www.export.gov/mrktresearch/index.asp
and http://www.ita.doc.gov/td/health/egyptregs.html

Ministry of Health & Population
Central Administration for Pharmaceuticals Affairs (CAPA)
21 Abdel Aziz Al Seoud St., Manial, Giza
Tel: +20 (2) 2364-8046, 2368-4183, 2368-4381
Email: capa@mohp.gov.eg; moh@idsc.gov.eg; webmaster@mohp.gov.eg
http://www.mohp.gov.eg

For More Information

The U.S. Commercial Service in Cairo, Egypt can be contacted via e-mail at: Jihan.Labib@mail.doc.gov; Phone: +20-2-2797-2688; Fax: +20-2-2795-8368 or visit our website: http://www.buyusa.gov/egypt/en.

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Comments and Suggestions: We welcome your comments and suggestions regarding this market research. You can e-mail us your comments/suggestions to: **Customer.Care@mail.doc.gov**. Please include the name of the applicable market research in your e-mail. We greatly appreciate your feedback.